

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV 335544995 US
Express Mail Label Number

November 5, 2003
Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

BLANK ET AL.

APPLICATION NO: Not Yet Assigned

FILED:

FOR: CONNECTOR DEVICE

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

CLAIM OF PRIORITY UNDER 35 USC §119

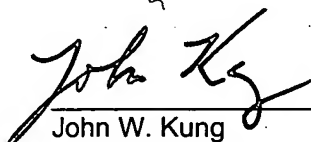
Sir:

Applicants in the above-identified application hereby claim priority under the International Convention of Great Britain Application No. 0226730.0, filed on November 18, 2002, and Great Britain Application No. 0229624.2, filed on December 19, 2002, and Great Britain Application No. 0303317.2, filed on February 13, 2003, and Great Britain Application No. 0311463.4, filed on May 19, 2003. These applications are acknowledged in the Declaration of the instant case.

The certified copies of said applications are submitted herewith.

Respectfully submitted,

Novartis
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Date: November 5, 2003



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INVESTOR IN PEOPLE

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I also certify that the attached copy of the request for grant of a Patent (Form 1/77) bears an amendment, effected by this office, following a request by the applicant and agreed to by the Comptroller-General.

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1. Your reference

N-32769P1

18NOV02 5764014-1 000524

P01/7700 0.00-0226730.0

2. Patent application number
(The Patent Office will fill in)

0226730.0

3. Full name, address and postcode of the
or of each applicant
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18 NOV 2002

Patent ADP number (if you know it)

If the applicant is a corporate body,
give the country/state of its
incorporation

SWITZERLAND

7143563001

4. Title of invention

Connector Device

5. Name of your agent (if you have one)
"Address for service" in the United
Kingdom to which all correspondence
should be sent
(including the postcode)Novartis Pharmaceuticals UK Ltd
Patents and Trademarks
Wimblehurst Road
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West Sussex
RH12 5AB ADP No 0718522002

Patents ADP number (if you know it)

6. If you are declaring priority from one
or more earlier patent applications,
give
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the or of each of these earlier
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Country

Priority application
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- a) any applicant named in part 3 is not an inventor, or
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(see note (d))

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Priority documents

Translations of priority documents

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(please specify)

11.

I/We request the grant of a patent on the basis of this application

Signature

Date

B. A. Yorke & Co.

B.A. Yorke & Co.

18 November 2002

12. Name and daytime telephone number of person to contact in the United Kingdom

Mrs. J. Crook
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DUPLICATE

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Connector Device

The present invention relates to a connector device, and in particular a sterile connector device, allowing connection between the feeding line of an enteral administration set and a laminated paper packaging system, such as Tetra Brick®, containing medical or nutritional fluids which can be intravenously or enterally administered to a patient.

Many individuals in hospitals or nursing homes cannot orally take nourishment or medication. These individuals, or medical patients, typically receive medical fluids containing the required nourishment and/or medication intravenously or enterally via a patient feeding line of an enteral administration set that is connected to a packaging system containing such medical or nutritional fluids. These medical or nutritional fluids are commonly packaged in flexible packaging systems, such as containers, for example flexible pouches. For economical and other reasons, such pouches may be disadvantageous.

Millions of laminated paper packaging systems, such as Tetra Brick®, are used in food industry. They provide a convenient cost-effective and lightweight paperboard solution, for every type of pourable, e.g. liquid, product. They exist in a myriad of sizes, from 0.2 liter to 1.5 liter, or even larger. Because they are opaque, they are perfect for light-sensitive enterally administrable compositions, for example enterally administrable compositions containing certain vitamins. Typically, medical fluids that are administered to a patient need to be sterile. Laminated paper packaging systems can be sterilized, and therefore keep even the most perishable liquid foods fresh, tasty and nutritious for months, without refrigeration or added preservatives. Finally, the laminated paper packaging systems can be aseptically and air tightly closed, preventing contaminants or oxygen from entering the container.

However, the existing enteral administration sets are not adapted to being connected, e.g. directly connected, to the existing laminated paper packaging systems. Consequently, medical or nutritional fluids have to be poured into an intermediate container which is then connected to the feeding line of an enteral administration set. This is inconvenient for patients and medical personnel. Moreover sterility is difficult to ensure.

In one aspect the present invention provides a connector device suitable for use with an existing enteral administration set and an existing laminated paper packaging system.

Such existing enteral administration sets, e.g. feeding lines, e.g. tube feeding lines, of enteral administration sets, and existing laminated paper packaging systems are well-known

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to one skilled in the art. For example, enteral administration sets are known and commercially available e.g. from Fresenius, Nutricia or Novartis Nutrition Corporation, e.g. under the trade name Compat® distributed by Novartis Nutrition Corporation Minneapolis, Minnesota). Examples for known and commercially available laminated paper packaging systems are Tetra® Brick, Tetra® Prisma, Tetra® Recart, Elopak®, Combiblok®, Pure Pak®, or those available from Toppan.

In a further aspect of the present invention there is provided an inexpensive and easily manufactured connector device. The connector device, for example, is of a unitary construction made entirely of a single material, for example a polymer.

The connector device according to the present invention may be sterilisable, e.g. retortable.

In a yet further aspect of the present invention there is provided a connector device for an enteral administration set and a laminated paper packaging system, e.g. containing a closure system, e.g. breakable closure system, comprising:

- (a) at least one means adapted to fit to the enteral administration set,
- (b) at least one means adapted to fit to the laminated paper packaging system, optionally to provoke the opening of, e.g. to break, the closure system when fitted, e.g. tightly fitted, to the laminated paper packaging system, and optionally
- (c) means to allow contact with the outside air when the connector device is fitted to the enteral administration set and to the laminated paper packaging system.

In another aspect of the present invention there is provided a device comprising an enteral administration set and a connector device connected thereto for a laminated paper packaging system, e.g. a laminated paper packaging system containing a closure system, e.g. a breakable closure system. Optionally such a device may comprise at least one means adapted to provoke the opening of, e.g. to break the closure system of the laminated paper packaging system when fitted thereto. Such a device may further comprise at least one means to allow contact with the outside air when the device is fitted to the laminated paper packaging system.

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In yet another aspect of the present invention there is provided a device comprising a laminated paper packaging system, e.g. containing a closure system, e.g. a breakable closure system and a connector device connected thereto for an enteral administration set. Optionally such a device may comprise at least one means adapted to provoke the opening, e.g. to break off, the closure system of the laminated paper packaging system. Such a device may further comprise at least one means to allow contact with the outside air when the device is fitted to the laminated paper packaging system.

The accompanying drawings, which are incorporated into and constitute part of the specification, illustrate exemplary embodiments of the present invention.

FIG. 1 is a front view of a connector device in connection with a feeding line of an enteral administration set and to a laminated paper packaging system in accordance with an embodiment of the present invention;

FIG. 2 is an enlargement of the connector device depicted in FIG. 1.

Referring to FIGS. 1 and 2, the connector device (1) may be connected to the feeding line (2) of an enteral administration set (3) and to a laminated paper packaging system (4). The connector device contains a section (5) which is adapted to the feeding line (2) of the enteral administration set (3), e.g. comprising means adapted thereof; on the opposite side a section (6) adapted to be connected to the laminated paper packaging system (4), e.g. comprising means adapted thereof; and optionally a valve system (7) positioned such as to be in contact with the outside air when the connector is fitted to the enteral administration set (3) and to the laminated paper packaging system (4). It will be appreciated that such valve system may also be positioned in the feeding line of the enteral administration set, or in the laminated paper packaging system.

The section (5) of the connector device adapted to the enteral administration set (3) may be fit, e.g. thread, into the feeding line (2) through a thread (8).

The valve system (7) may contain an air filter (9) to prevent contaminants from entering the patient feeding line.

The laminated paper packaging system (4) contains a medical fluid providing medication and/or nutrition to a patient. It may be for example of the type Tetra Brik®, Tetra® Prisma, Tetra® Recart, Elopak®, Combiblok®, Pure Pak®. Such laminated paper packaging systems may be made of cardboard with waterproofing on at least its internal

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surface by techniques known by the skilled in the art, e.g. by means of a lamina or coating of an olefin polymer. It may contain a closure system (10), e.g. seal, defeatable in some manner, for example by removal or by penetration, e.g. a breakable closure system, e.g. a frangible barrier layer material. In one embodiment of the invention such a closure system may be hermetic. This closure system (10) may be opaque. It can also be made of a material that has no or low permeability to oxygen. Suitable breakable closure systems are known to one skilled in the art and include, but are not limited to, for example, polymeric membrane or aluminum foil. It will be appreciated that one skilled in the art is fully enabled to select a suitable material. The breakable, e.g. hermetic closure system (10) of the laminated paper packaging system (4) may be covered by a cap (11), e.g. a twist-off or screw cap, e.g. of the type spin® cap or stream® cap, or a snap-on cap. According to the present invention, the connector device (1) may be connected directly to the laminated paper packaging system (4). Alternatively, such a connection may also be made through the cap (11) of the laminated paper packaging system (4), for example through an internal thread (12a) of the connector device interacting with an external thread (12b) of the cap (11), or any other structure known in the art.

In one embodiment of the invention, the connector device (1) contains a system e.g. perforating system, (13) adapted to break, e.g. puncture, the breakable closure system (10) of the laminated paper packaging system (4). This perforating system may consist of one or more spikes (14), cutting teeth, or of any other structure known to one skilled in the art. The perforating system may be brought into contact with the breakable closure system (10) when fitting the connector device (1) thereto. Such a contact may be made by pressing the connector device (1) to the laminated paper packaging system (4), or alternatively by fitting it, e.g. screwing it, onto the cap (11) of the laminated paper packaging system.

In another embodiment of the invention, the breakable closure system (10) of the laminated paper packaging system (4) may be broken by a perforating system (15) associated with, e.g. incorporated into, the cap (11) of the laminated paper packaging system (4). Such perforating systems are known in the art and include, but are not limited to, for example, perforating systems associated with caps, e.g. twist-off or screw caps, e.g. of the type spin® cap or stream® cap, or snap-on caps. Preferably the perforating systems may be associated with twist-off caps or screw caps. Typically, such a perforating system may be brought into contact with the breakable, e.g. hermetic, closure system (10) by

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screwing onto the cap of the laminated paper packaging system or by pressing it. According to the present invention, the perforating system may be triggered by fitting section (6) of the connector device, e.g. means thereof, to the laminated paper packaging system, e.g. to the cap (11) thereof. In one embodiment, section (6) of the connector device, adapted to being connected to the laminated paper packaging system, contains at least one triggering system (16) capable of interacting with the perforating system (15) of the laminated paper packaging system (4) to shift it in direction to the closure system (10), provoking its break. Such triggering system may be an extending, e.g. an downwardly extending, system. It may consist of or comprise at least one means, e.g. arm, capable of interacting with the perforating system (15) of the laminated paper packaging system (4). Such triggering systems are known by one skilled in the art.

In one embodiment of the invention, the triggering system may be provoked by fitting the connector device to the laminated paper packaging system by means known by one skilled in the art, for example by leverage or reverse thread.

The tightness between the connector device (1) and the laminated paper packaging system (4) may be ensured by means, e.g. systems, known in the art, e.g. applied either on top, inside or outside of the connector device, such as so-called "olive tightness type", by foam or direct top contact. Such technical devices are known by one skilled in the art, it will be appreciated that one skilled in the art is fully enabled to select a suitable tightness system.

In a further embodiment of the invention, the connector device may be reversibly or irreversibly connected to the feeding line of an enteral administration set. The irreversible connection of the connector device to the feeding line may be made by methods including, but not limited to, heat induction, ultrasonic welding and friction welding or any other methods as known in the art. In this case the appropriate material of the connector device may be capable of forming an airtight seal with the material from which the feeding line of the enteral administration set is made. The connector device may also be molded to the feeding line of an enteral administration set as a single unitary construction.

The connector device of the present invention may be made from a plastic or polymeric material, including but not limited to polyolefine, e.g. polypropylene or

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polyethylene. The connector device of the present invention may be made from a material that has low permeability to oxygen.

The connector device as described hereinabove may also be reversibly or irreversibly connected to the laminated paper packaging system. Preferably, the connector device as described hereinabove is irreversibly connected to the enteral administration set.

Hence, the present invention also pertains to a connector device as hereinabove described connected to the feeding line of an enteral administration set. In a further aspect the present invention also pertains to a connector device as hereinabove described connected to a laminated paper packaging system.

The connector device as hereinabove described allows convenient, safe, and economically advantageous administration of a medical or nutritional liquid food to a patient in need thereof.

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Claims

1. A connector device for an enteral administration set and a laminated paper packaging system comprising:
 - (a) means adapted to fit to the enteral administration set,
 - (b) means adapted to fit to the laminated paper packaging system, and optionally
 - (c) means to allow contact with the outside air when the connector device is fitted to the enteral administration set and to the laminated paper packaging system.
2. A connector device for an enteral administration set and a laminated paper packaging system containing a closure system comprising:
 - (a) means adapted to fit to the enteral administration set,
 - (b) means adapted to fit to the laminated paper packaging system, optionally
 - (c) means adapted to provoke the opening of the closure system when the connector device is fitted to the laminated paper packaging system, and optionally
 - (d) means to allow contact with the outside air when the connector device is fitted to the enteral administration set and to the laminated paper packaging system.
3. A connector device for an enteral administration set and a laminated paper packaging system containing a breakable closure system comprising:
 - (a) means adapted to fit to the enteral administration set,
 - (b) means adapted to fit to the laminated paper packaging system in the area of the breakable closure system and to provoke the break of the closure system when fitted to the laminated paper packaging system, and optionally
 - (c) means to allow contact with the outside air when the connector device is fitted to the enteral administration set and to the laminated paper packaging system.
4. The connector device according to claim 2 or 3 wherein the means adapted to fit to the laminated paper packaging system contains a perforating system adapted to break the breakable closure system of the laminated paper packaging system.
5. The connector device according to claim 4 wherein the perforating system of the connector device comprises at least one spike.

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6. The connector device according to any one of claims 1 to 5 for a laminated paper packaging system containing a closure system covered by a cap.
7. The connector device according to claim 6 wherein the connector device is adapted to trigger a perforating system incorporated into the cap of the laminated paper packaging system.
8. The connector device according to claim 7 wherein the connector device contains means to trigger the perforating system of the laminated paper packaging system.
9. The connector device according to claim 8 wherein the connector device contains at least one downwardly extending means capable of interacting with the perforating system of the laminated paper packaging system.
10. Connector device suitable for directly connecting an enteral administration set to a laminated paper packaging system.
11. Use of connector device according to any preceding claim to connect a laminated paper packaging system to an enteral administration set.
12. A device comprising an enteral administration set and the connector device of any one of claims 1 to 10 connected thereto.
13. A device comprising a laminated paper packaging system and the connector device of any one of claims 1 to 10 connected thereto.
14. Method of enterally administering to a patient in need thereof a pourable medical or nutritional food contained in a laminated paper packaging system which method comprises connecting the feeding line of the enteral administration set to the laminated paper packaging system through a connector device according to any one of claims 1 to 10.

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15. A connector device or device as claimed in any one of claims 1 to 10 or claims 12 and 13
16. , substantially as hereinbefore described with reference to any one of the accompanying figures.

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ABSTRACT

The present invention relates to a connector device suitable for connecting an enteral administration set to a laminated paper packaging system containing intravenously or enterally administrable medical or nutritional food.

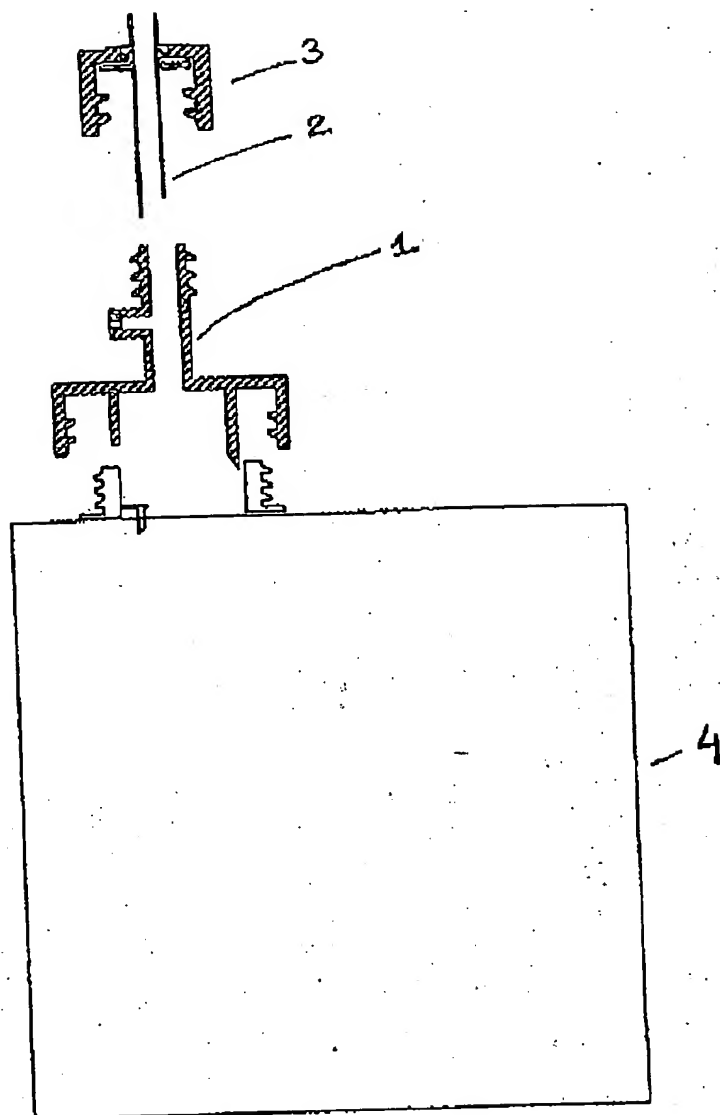
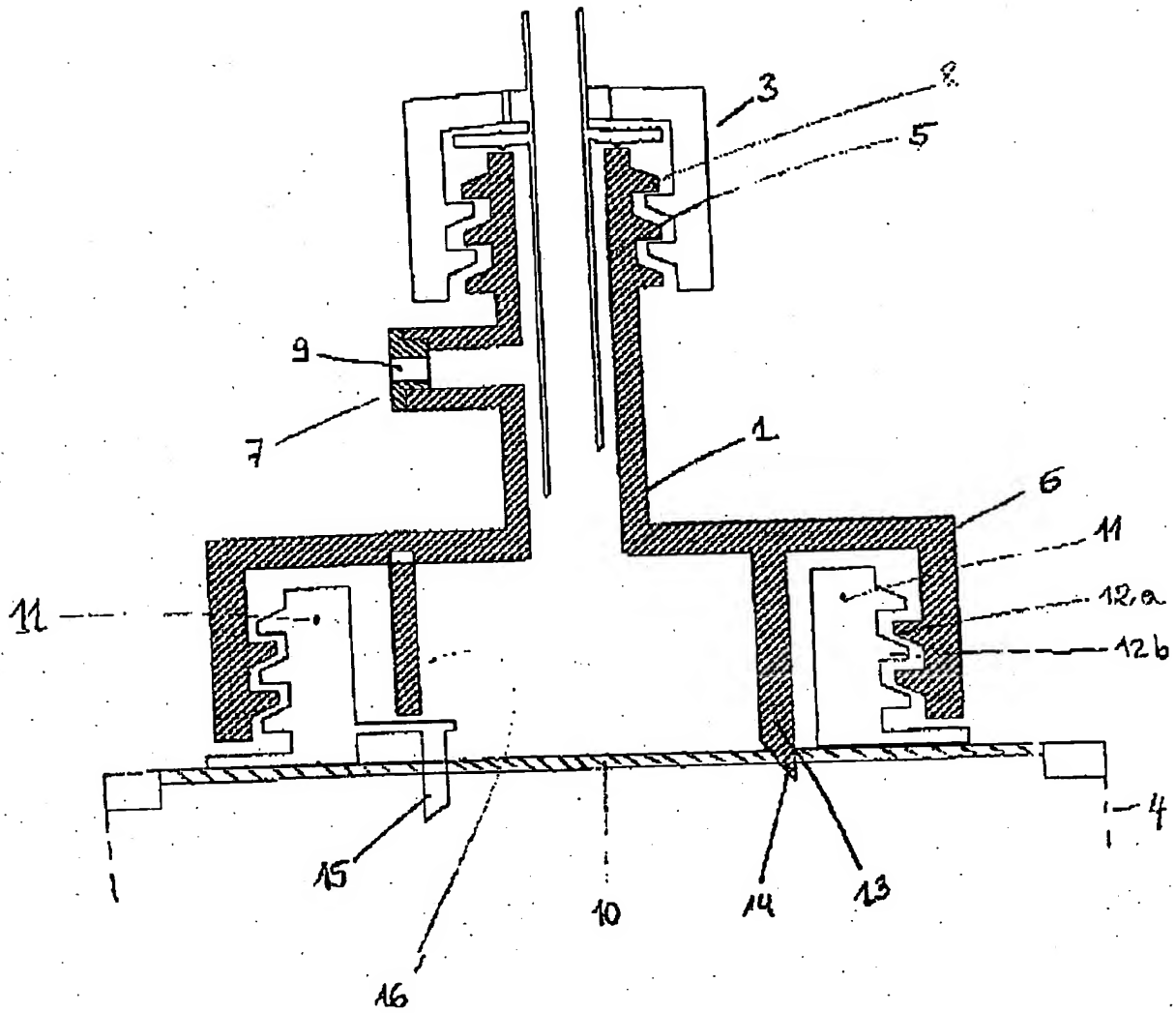


FIG. 1



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INVENTOR



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